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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,961	10/16/2000	Patrick Rambaud	USB00 RBA PIC	5796

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YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/19/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/685,961	RAMBAUD, PATRICK	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-4,6-7,10-25,27-29,35-36* is/are pending in the application.

4a) Of the above claim(s) *10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7,20-25,27-29,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3-4, 6-7, 10-25, 27-29, 35-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Claims 10-19 remain withdrawn from further consideration. Election was made **without** traverse in Paper No. 5.

Specification

The abstract of the disclosure is objected to because it is not in narrative form and contains multiple paragraphs. Correction is required. See MPEP § 608.01(b).

Drawings

The formal drawings filed 5/14/02 have been approved by the draftsman.

Claim Rejections - 35 USC § 112

Claims 1, 3-4, 6-7, 20-25, 27-29, and 35-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a written description and enablement rejection.

Claims 1, 3, 20, 22, 23, 35, and 36 have been amended. No basis has been pointed to for these new limitations and none is apparent. In the absence of support, these claims and claims dependent thereon are deemed to constitute new matter.

Claim 1 requires processing status-characterizing information for determining the subject's identity data and determining parameters of a deferred-use protocol for immunocompetent cells. The specification fails to disclose how status-characterizing information is to be processed to determine a subject's identity data. What is the content of this

identity data? It does not appear to be just who the subject is and the status-characterizing information. The specification fails to disclose what information the deferred-use protocol is to provide. The specification does not define or suggest how to determine any parameters. There is no explanation as to how the information collected is to be used to arrive at the desired goal. For example, assume three batches of immunocompetent cells from subject A were conditioned and preserved at time points X, Y, and Z. Assume that measurements of levels of zinc in hair samples from subject A are gathered at time points X, Y, and Z. All of this information is stored into a cell management database. How is this information supposed to be processed to determine any parameter of a deferred-use protocol? What information must be determined to meet the limitation of a deferred-use protocol? The specification doesn't make clear if the method is attempting to determine which (if any) of the successive batches can be re-used at some point in time or under certain conditions or for particular medical conditions or something else.

In particular, claim 6 requires an expert system used for determining parameters for deferred-use protocols. No such expert system is disclosed as being known in the art by the specification. As such, the expert system would need to be developed. Note that an expert system is not a particular software or hardware product that is commercially available and immediately applicable to any problem. Such systems must be developed with consideration of the problem at hand, the input to be used, and the desired output. Sufficient information must be known to build, test, and validate a model for a particular problem. All of this is absent from the instant application.

The instant application is an invitation to experiment to determine a deferred-use protocol and parameters thereof without any explanation of what the desired end goal is and without any

clear explanation of what the input is (i.e. subject's identity data). The specification provides no actual example of the claimed methods or systems. The specification does not provide any concrete example of the intent of the claimed methods or systems. The block diagrams or black boxes in the figures do not remedy the absence of disclosure as to what information to use and what information to find and how to do it. One of ordinary skill in the art attempting to practice the invention would not know with any particularity what they were trying to do.

Claims 1, 3-4, 6-7, 20-22, and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method of claim 1 appears to be directed to the following steps:

a. condition and preserve batches of immunocompetent cells AND

b. constitute and enhance a personal library of immunocompetent cells OR

c. gather information characteristic of the subject

d. process information

e. store information in database

f. identify personal batches of cells from information stored in database AND

g. determine parameters of a deferred-use protocol.

First of all, the preamble goal of the method of claim 1 is "managing batches of immunocompetent cells." However, the final step is determining parameters of a deferred-use protocol. Thus, the steps of the method are inconsistent with the goal of the method. Secondly, the use of "and" and "or" is confusing. It is unclear which steps must be performed. That is, are

steps (a and b) or step c performed or are step a and step (b or c) performed? It appears that all of the steps are intended to be performed but the claims do not set forth this concept. Note also that the final step of determining parameters are never output, saved, or in any way communicated to a user.

Claim 3 recites "(Vincent's bioelectronic method)." It is unclear whether the claim is limited to this method or whether this is an example of a method.

Claim 4 recites "sensible crystallization images of blood." It is unknown what this is.

Claim 7 recites "said expert system is arranged for providing an interpretation...with respect to a particular gene." It is unclear what structural or functional limitation (i.e. hardware, software) is required. It is unclear whether the method is required to produce the recited interpretation, output this information, save this information, etc. In addition, claims 1 and 6 do not require any information about a gene to be gathered for analysis. See also claim 29.

Claim 20 recites "before the step for cryo-preserving." However, there is no antecedent basis for cryo-preserving in claim 1. Claim 20 also recites "in view of annihilating antibodies." It is not known what is meant by this limitation. It is unclear whether the cryogenizing step occurs in all cases or only if certain conditions (i.e. presence of annihilating antibodies) are met.

Claim 28 recites "means for controlling and enhancing an expert system...in view of determining parameters for deferred-use protocols." It is unknown what structural or functional limitation (i.e. hardware, software) is required to meet the limitations of "controlling and enhancing." It is not known what the metes and bounds are for "enhancing an expert system." (Make it run faster, more efficiently, modify results, something else?) Claim 28 is a system and

Marianne P. Allen
Primary Examiner
Art Unit 1631

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